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The Updated Drug Labeling for Patient Safety Act

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Prescription Drug Labeling in the United States

Prescription drugs typically come to market as a brand-name product and then—after the branded drug's exclusivity period elapses—generic versions of that same drug enter the marketplace. The availability of generic drugs makes medications more affordable for patients, so generics are widely used and capture most of the market share once they become available.

Both brand-name prescription drugs and their generic counterparts are required to carry warning labels by the Food and Drug Administration (FDA). The warning and precautions section on a prescription drug label is used to convey serious potential safety hazards associated with taking the drug to health care providers and patients so that they can make informed health care decisions and minimize any risks associated with taking a particular prescription.

Current FDA regulations require a generic drug to have the same labeling as its brand-name counterpart with very limited exceptions. While brand-name drug manufacturers are permitted to update their product labels to add new safety warnings without prior FDA approval, generic manufacturers cannot independently update the labeling for their products—even if they become aware of health risks not represented on the labeling. Yet brand-name manufacturers have decreased incentive to monitor drug safety and initiate labeling updates after generics enter the market because of their drastically decreased market share. Sometimes, brand-name manufacturers even withdraw their products from the market altogether, leaving no manufacturer with the ability to initiate labeling updates with newly discovered risks.

However, many potential risks and side effects are not discovered until years after a drug first enters the market and after generics are available. For instance, the prescription pain reliever Naproxen Sodium was approved in 1987 and has been available in generic form since 2007. In May 2016—nearly 30 years after initial approval—a boxed warning was added concerning the risk of serious cardiovascular and gastrointestinal events. In August 2017, a new warning was added concerning an increased risk of heart attack and stroke.

With over four in five prescriptions in the United States filled by generic drugs, the restriction on generic manufacturers being able to update labeling creates a safety gap. In addition, because generic drug manufacturers usually cannot be held accountable for inadequate safety labeling, patients who take generic drugs have limited legal recourse if they experience harm due to undisclosed safety issues.

To address this safety gap, the FDA in 2013 proposed a new rule (never finalized) to allow safety updates to generic drug labeling, similar to the process used for brand-name drugs. This would have enabled all manufacturers to update labeling promptly to warn about clinically significant hazards as soon as there is reasonable evidence of a causal association with a drug. As the FDA recognized, allowing generic drug manufacturers to initiate safety updates is critical to improving communication of important drug safety information to health care providers and the public.

The Solution

The Updated Drug Labeling for Patient Safety Act would direct the FDA to:

- Issue a final rule establishing a process allowing generic drug manufacturers to update drug labeling to include new or updated safety-related information for their products, and to conform the labeling of each brand-name and generic drug product.
- Implement the final rule promptly within 180 days of issuance.

Endorsements

The Updated Drug Labeling for Patient Safety Act is endorsed by the American Association for Justice and Public Citizen.